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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/825,537 | 04/15/2004 | Andrew L. Chen | ORTHO-001US | 8235 |

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| EXAMINER | |
|---|---|
| GHALI, ISIS A D | |

| ART UNIT | PAPER NUMBER |
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| 1611 | |

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| 05/06/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/825,537 | CHEN, ANDREW L. | |
| | Examiner | Art Unit | |
| | Isis A. Ghali | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *1-17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The receipt is acknowledged of applicant's election filed 01/23/2008.

Claims 1-20 are pending.

### *Election/Restrictions*

Upon further review and reconsideration, the species election of transdermal component within the Markush group claimed by claim 2 has been withdrawn.

1. Applicant's election without traverse of invention I (claims 1-19), and species aqueous carrier (claim 13), and cream (claim 17), in the reply filed on 01/23/2008 is acknowledged.

2. Claims 18-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/123/2008.

Claims 1-17 are included in the prosecution.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the article "A Randomized, Double Blind, Placebo Controlled Trial of a Topical Cream Containing Glucosamine Sulfate, Chondroitin Sulfate, and Camphor for Osteoarthritis of the Knee" by Cohen et al. in view of US 6,645,520 ('520).

Cohen et al. teaches topical formulation for treating osteoarthritis comprising water soluble (aqueous) cream containing glucosamine, chondroitin sulfate, camphor and peppermint oil, and further containing emollient and emulsifier that both read on transdermal component (page 524, left column, second full paragraph).

Cohen et al., however do not teach an anti-inflammatory agent as claimed by claims 1 and 4, or the ingredients of the composition as claimed by claims 3, 5-16.

US '520 teaches transdermal formulation having enhanced skin permeation to deliver nonsteroidal anti-inflammatory drugs (NSAID) to the skin to treat osteoarthritis, rheumatic and rheumatoid arthritis without systemic toxicity (abstract; col.2, lines 65-67; col.15, lines 56-67). The formulation can be aqueous formulation and can be in the form of cream (col.29, claims 6 and 11). NSAID includes salicylic acid, ibuprofen and ketoprofen (col.31-32, claims 42-45). The formulation comprises benzyl alcohol which

reads on transdermal component claimed by claim 2 (col.12, line 35); DMSO, i.e. methylsulfonylmethane that reads on transdermal component and anti-pruritic agent claimed by claims 2, 5 and 6 (col.12, line 46); citric acid that reads on viscosity adjusting agents claimed by claims 7 and 8 (col.12, line 45); ethyl oleate that reads on solubility adjusting agent claimed by claims 9 and 10 (col.12, lines 37-38); glycerin and vitamin E that both read on emollient claimed by claim 11 (col.12, lines 57-59); and lecithin that reads on emulsifier claimed by claims 14 and 15 (col.10, line 43; col.12, line 33).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cream formulation comprising glucosamine, chondroitin sulfate, camphor, and peppermint oil to treat osteoarthritis as taught by Cohen et al., and add NSAID selected from salicylic acid, ibuprofen and ketoprofen and further add other conventional ingredients known to be used in transdermal formulations taught by US '520 because US '520 teaches such transdermal formulation provides enhanced permeation of NSAID through the skin without systemic toxicity and also treats osteoarthritis, with reasonable expectation of having cream formulation comprising glucosamine, chondroitin sulfate, camphor, peppermint oil, NSAID and transdermal component that effectively penetrates the skin and synergistically treats osteoarthritis without undesired toxic systemic effects.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

Cohen does not explicitly teach the exact amounts of different ingredients as instantly claimed. However, those of ordinary skill in the art would have been readily optimized effective dosages as determined by good medical practice and the clinical condition of the individual patient. Determination of the appropriate dosage for treatment involving each of the above mentioned ingredients would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the dosage information disclosed prior art.

5. Claims 1-7, 9-14, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. in combination with US 6,399,093 ('093).

Cohen et al. teaches topical formulation for treating osteoarthritis comprising water soluble (aqueous) cream containing glucosamine, chondroitin sulfate, camphor and peppermint oil, and further containing emollient and emulsifier that both read on transdermal component (page 524, left column, second full paragraph).

Cohen et al., however do not teach an anti-inflammatory agent as claimed by claims 1 and 4, or the conventional ingredients of topical composition as claimed by the rest of dependent claims.

US '093 teaches topical formulation for treating musculoskeletal disorders in mammals that provides anti-inflammatory relief and analgesia to the applied body part (abstract). The formulation comprises 5% ibuprofen; 15% aloe vera that reads on emollient claimed by claim 11; 20% propylene glycol that reads on viscosity adjusting

agent of claim 7, reads on solubility adjusting agent claimed by claims 9 and 10, and reads on emollients claimed by claim 11; 20% glucosamine sulfate; 10% methylsulfonylmethane that reads on transdermal component claimed by claims 2 and 3 and on anti-pruritic agent claimed by claims 5 and 6; and water (example 1, col.12). Example 1 shows aqueous formulation containing water. The formulation can be in the form of cream (col.3, line 24). US '093 teaches that the topical composition may further comprise menthol, camphor, and chondroitin sulfate that has chondroprotective effect (col.3, lines 45-53; col.11, lines 6-7, 44-47).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cream formulation comprising glucosamine, chondroitin sulfate, camphor, peppermint oil and transdermal component to treat osteoarthritis as taught by Cohen et al., and add ibuprofen and further add other conventional ingredients known to be used in transdermal formulations taught by US '093 because US '093 teaches NSAID can be administered with glucosamine in topical formulation and the combination provides treatment for musculoskeletal disorders in mammals and provides anti-inflammatory relief and analgesia to the applied body part, with reasonable expectation of having cream formulation comprising glucosamine, chondroitin sulfate, camphor, peppermint oil, NSAID and transdermal component that effectively treats musculoskeletal disorders and provides anti-inflammatory relief and analgesia to the applied body part.

6. Claims 8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. combined with US '093 and further in view of US '520.

The teachings of the references are previously discussed as set forth in this office action.

The combination of Cohen and US '093 are discussed in section 5 of this office action.

Although Cohen combined teach viscosity adjusting agents and emulsifier in the composition, however, the combination of the references does not explicitly teach the specific viscosity adjusting agent as claimed by claim 8 or the specific emulsifier as claimed by claim 15. US '520 teaches citric acid and lecithin in topical composition to deliver NSAID to treat osteoarthritis, as set forth in section 4 of his office action.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide cream formulation comprising glucosamine, chondroitin sulfate, camphor, peppermint oil, NSAID and transdermal component including viscosity adjusting agent and emulsifier as disclosed by the combined teachings of Cohen and US '093, and further replace the viscosity adjusting agent with citric acid and replace the emulsifier with lecithin as taught by US '520 because US '520 teaches transdermal formulation comprising such ingredients treats osteoarthritis and provides enhanced permeation of NSAID through the skin without systemic toxicity, with reasonable expectation of having cream formulation comprising glucosamine, chondroitin sulfate, camphor, peppermint oil, NSAID, transdermal component, citric acid

and lecithin that effectively penetrates the skin and synergistically treats osteoarthritis without undesired toxic systemic effects.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611